REMARKS

Claims 32-37, 39-62 and 71-116, 118, and 119-125 are pending in the instant application. Claims 32-37, 42, 44-62, 115, 116 and 118 are allowed. Claims 39-41, 43, 71-114, and 119 stand rejected. Claims 71-81 are objected to. The specification is objected to. Claims 39-41, 43, 71-81, and 119 are amended herein. Support for these amendments can be found on at page 3, lines 25-29, page 9, line 31 through page 11, line 30, page 12, line 29 through page 13, line 13, page 14, lines 9-15 as well as throughout the Examples. Claims 120-125 are added herein. Support for newly added claims 120-125 can be found at page 12, lines 3-10 as well as in Example 4, pages 23-26 of the specification. Thus, no new matter has been added.

In view of the following amendment and response, the Applicant believes the claims presented herein are allowable. Reconsideration is respectfully requested.

SPECIFICATION OBJECTIONS

The specification is objected to for allegedly failing to provide proper antecedent basis for the claimed subject matter. The Examiner suggests the insertion of an additional sentence disclaiming saponin-derived immunostimulants at the end of the last paragraph of page 5 to overcome the rejection. Applicant respectfully traverses this objection. Applicant respectfully submits that written description and enablement of the specification must relate to the claims. See MPEP § 706 and 37 CFR § 1.104(c)(1). According to 35 U.S.C. § 112, first paragraph, the specification must contain a written description of the invention. As discussed in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991), "The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention." (emphasis added).

Applicant further submits that an inventor does not need to support what is not claimed. See *Engel Insustries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 U.S.P.Q.2d 1300, 1302 (Fed. Cir. 1991) (unclaimed subject matter is not subject to the disclosure requirements of § 112, only the inventions defined by the claims need be explained in the patent application in a manner sufficient to be supported as required by 35 U.S.C. §112, first paragraph). Therefore, a proviso excluding certain adjuvants from the claimed invention is not subject to the same requirements of 25 U.S.C. § 112 as claimed subject matter. The specification discloses in several places various examples of immunostimulants, including Monophosphoryl lipid A, CpG, and saponins, see page 6 of the specification. Thus, Applicant discloses saponins within the specification, but the law does not require her to disclaim saponins within the specification in order to disclaim certain saponins within the claims. Therefore, Applicant requests that the objection to the specification be withdrawn.

The specification is also objected to for allegedly not providing antecedent basis for the claim language identifying LnRH(GnRH) as an antigen. The Examiner indicates that the objection may be overcome by either pointing out where support for the claim language is in the specification or amending the specification to provide such antecedent basis. Applicant has amended the specification herein to include the term"LnRH(GnRH)," within the specification at page 13. Support for this amendment can be found in claims 11 and 22 as originally filed. Applicant requests that the objection to the specification on this basis be withdrawn.

The specification is also objected to for the informality of referring to the vaccine HiB by its acronym. Applicant has amended the specification herein to include the full name of HiB at page 9, line 11 as *Haemophilus influenzae* Type B ("HiB"). "*H. influenzae* Type B" is also disclosed at page 20 of the specification without the abbreviation "HiB." Thus, Applicant respectfully request that this objection be withdrawn.

CLAIM OBJECTIONS

Claims 71-81 are objected to for the informality of identifying Hib and LnRh(GnRH) as antigens and not identifying them by their complete name. Applicant has amended claims 71-81 herein to recite "*Haemophilus influenzae* Type B ("HiB")" in place of "HiB" in claims 71-81 as well as in claim 41. However, Applicants respectfully submits that both abbreviations, HiB and LnRH(GnRH), are well understood in the art. The term "LnRH(GnRH)" is disclosed in the original claims of the application. Using the term "LnRH(GnRH)" instead of the full name of the hormone is similar to expressing "water" as "H_2O." Its meaning is understood by the skilled artisan, thus, writing the term in long-form does not clarify its meaning further. Therefore, Applicant has not amended claims 71-81 to include the unabbreviated term for LnRH(GnRH). Applicant respectfully requests that objection to these claims be withdrawn.

35 U.S.C. §112, FIRST PARAGRAPH

Claims 41, 43, 71-81 and 93-114 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabling for vaccines against all the identified pathogens. In particular, the Examiner alleges that, "for several of these pathogenic sources, no vaccines are currently known or recognized. See e.g. Perbandt *et al.* JBC Papers in Press, September 2003." However, Examiner states that Applicant would be enabled for "immunogenic compositions." Applicant respectfully traverses this rejection. However, in an effort to advance prosecution and in response to addition rejections made under 35 U.S.C. §112, second paragraph, discussed below, claims 41, 43, and 71-81 are amended herein. Claims 41 and 71-81, as amended, recite an antigen that "elicits an immune response to a pathogen, polypeptide, or anti-tumour antigen selected from the group of." Thus, the claims recite vaccine compositions that comprise an

antigen that elicits an immune response or is immunogenic. Support for these amendments can be found at page 9, lines 31-32, page 14, lines 9-15, and Example 2 starting on page 17 of the specification. In addition, claim 43 is amended herein to include the term "composition" after the term "vaccine." Applicant respectfully submits that these claims are now in condition for allowance. As claims 91-114 depend from claims 71-81, Applicant also submits that these claims are also in condition for allowance.

Claims 39-41, 43 and 119 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the Examiner alleges that, "the specification and the original claims disclose the claimed invention as comprising immuostimulants absorbed to a metallic salt particle that is substantially free of antigen." The Examiner goes on to allege that, "the identified claims do not require that the salt particles to which the immunostimulant is absorbed are free of antigen." Applicant amends claims 39-40 and 119 to recite that the immunostimuant is "substantially free of antigen." In addition, claims 41 and 43 depend from claims 39 to 40, thus, Applicant respectfully submits that claims 41 and 43 are also in condition for allowance. Support for these amendments can be found at page 3, lines 25-29.

Applicant respectfully submits that in view of the forgoing remarks and the claims as amended, the Applicant has overcome the Examiner's rejection under 35 U.S.C. §112, first paragraph, and that rejection should be withdrawn.

35 U.S.C. §112, SECOND PARAGRAPH

Claims 71-81 and 104-114 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner alleges that these claims appear to be Markush type claims. However, the Examiner alleges that the term "comprising" should be

substituted with the term "consisting of." Applicant herein amends claims 71-81, replacing the term "comprising" in each claims with the term "consisting of." In addition, Applicant has amended claims 71-81 to recite the inclusive term "and" rather than the term "or" within the list of terms as is typical in a Markush-type claim. Furthermore, claims 104-114 depend from claims 71-81 respectively and are therefore subject to the same amended language. Applicant believes that, as amended, claims 71-81 and 104-114 overcome rejection under 35 U.S.C. §112, second paragraph for the reasons noted above.

Claims 71-81 and 104-114 also stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner alleges that these claims identify LnRH(GnRH) as an antigen. The Examiner cites U.S. Patent 6,559,282 as identifying Luteinizing Hormone Releasing Hormone (LHRH) also known as Gonadotropin-releasing hormone (GnRH), suggesting that the art indicates that the Applicant may have misidentified the claimed antigen. Applicant respectfully submits that Luteinizing Hormone Releasing Hormone is known in the art as both LnRH and LHRH. See for instance the attached web page from the NCBI that lists both LHRH and LnRH as aliases for GNRH. Thus, Applicant respectfully submits that the term LnRH(GnRH) is known in the art as having the same meaning as LHRH(GnRH). Both terms identify luteinizing hormone releasing hormone (gonadotropin releasing hormone) or simply gonadotropin-releasing hormone. Applicant has not amended the term in the claims as both abbreviations are known in the art.

Claims 71-81 and 104-114 are also rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner alleges that these claims identify "viruses and microbial genera without indicating that the antigen may be from or

to these pathogens, rather than comprising the pathogen themselves." The Examiner alleges that it is unclear if the antigen must comprise the pathogen. Applicant has herein amended claims 71-81 to recite an antigen that "elicits an immune response to a pathogen, polypeptide, or anti-tumour antigen selected from the group of." Support for this amendment can be found at page 9, line 31 through page 11, line 30. Additional support can also be found at page 12, line 29 through page 13, line 13 as well as throughout the Examples and original claims. As is understood in the art and discussed within the specification at page 9 through page 12 and page 13, lines 14-24, an antigen may include a whole pathogen or pathogen derived antigen or a derivative or fragment of a pathogen, polypeptide, nucleic acid, or chimeric fusion protein. Claims 71-82 recite specific antigens that elicit immune response, and these antigen may be derivatives or fragments of the pathogens of proteins recited. Applicant believes that amended claims 71-81 overcome any rejection under 35 U.S. C 112, second paragraph. As claims 104-114 depend from claims 71-81, Applicants believe these claims to be in condition for allowance as well.

Claims 83-103 also stand rejected under 35 U.S. C 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. In particular, the Examiner alleges the claims have insufficient antecedent basis for the limitations identifying specific subparticles of an antigen when the claims depend from "one of claims 71-82, which indicates that the antigens of the compositions comprise the whole of the identified pathogens." Applicant respectfully submits that claims 71-82 are amended herein to recite a vaccine composition comprising an antigen that "elicits an immune response to a pathogen, polypeptide, or anti-tumour antigen selected from the group of." Thus, the claims from which claims 83-103 depend are now directed to antigens that elicit an immune response to one of the listed pathogens or anti-tumour antigens recited in claims

71-82. As discussed above, an antigen may include a whole pathogen or pathogen derived antigen or a derivative or fragment of a pathogen, polypeptide, nucleic acid, or chimeric fusion protein. Claims 71-82 recite specific antigens that elicit immune response, and these antigen may be derivatives or fragments of the pathogens of proteins recited. Thus, claims 71-81 provide sufficient antecedent basis for claims 83-103 which claim combinations of such antigens.

Claims 93-103 stand rejected under 35 U.S. C 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. In particular, the Examiner alleges that the claims read on an invention wherein the antigen is a plasmodium antigen. However, the Examiner alleges that the claims are indefinite in that the claim "appears to be including S antigen as one of the Plasmodium antigens."

Applicant respectfully traverse this rejection. Applicant respectfully submits that RTS, S is described at page 12 lines 11-28 of the specification as a plasmodium antigen. RTS, S includes RTS which is a hybrid protein comprising substantially all of the C-terminal portion of the circumsporocoite (CS) protein of *P. falciparum* linked to the surface (S) antigen of hepatitis B. Coexpression of RTS with S antigen from HBV produces a mixed particle known as RTS, S, which is a plasmodium antigen. The specification also includes WO 93/10152 by reference, which describes RTS, S. Thus, Applicant respectfully submits that as described in the specification and references, RTS, S is a hybrid of an antigen from *P. falciparum* and S antigen from hepatitis B and therefore, comprises a plasmodium antigen.

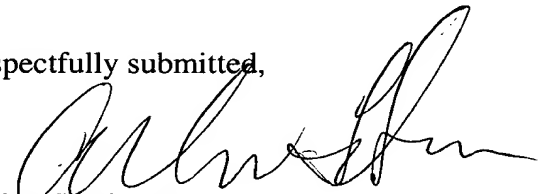
The Applicant respectfully submits that in view of the forgoing remarks and the claims as amended, the Applicant has overcome the Examiner's rejection under 35 U.S.C. §112, second paragraph, and that rejection should be withdrawn.

35 U.S.C. § 102

Claims 43 stands rejected under 35 U.S.C. . § 102(a) as allegedly being anticipated by Hauser *et al.*, U.S. Patent 5,776,468. In particular, the Examiner alleges that because claim 43 does not specify that the metallic salt to which the immunostimulant is absorbed in substantially free of other antigen, it is anticipated by Hauser, *et al.* The Examiner indicates that Hauser, *et al.* teach a composition comprising and immunostimulant, a metallic salt and an antigen at Col.1, liens 45-53. Applicant herein amends claims 39-41 to recite an adjuvant composition wherein the first metallic salt particle is "substantially free of antigen." As claim 43 depends from claims 39-41, Applicant believes these amendments render the Examiner's rejection under 35 U.S.C. 102(a) moot.

If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicant's undersigned attorney.

Respectfully submitted,



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			Nucleotide:	X15215, M12578, X01059, none		
			Protein:	AAA35916, CAA25526, CAA33285, NP_000816, P01148		

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